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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,053	04/06/2000	James W. Williams	29666/35415	1413

7590 05/29/2002
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EXAMINER

WANG, SHENGJUN

ART UNIT PAPER NUMBER

1617

DATE MAILED: 05/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/529,053

Applicant(s)

WILLIAMS ET AL.

Examiner

Shengjun Wang

Art Unit

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Peri d for Reply
-- The MAILING DATE of this communication appears on the c ver sheet with th c rrespondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2002 .
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9 .
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____ .

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DETAILED ACTION

Receipt of applicants' amendments and remarks submitted March 21, 2002 is acknowledged.

Claim Rejections 35 U.S.C. 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 16-17, 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weithmann et al. (US Patent 5,556,870) in view of Flamand et al. (CAPLUS Abstract, AN 1991:581163), Hammer (AIDS 1996, vol. 10, suppl 3, s1-s11) for reasons as set forth in the prior office action.

3. Claims ~~1-13~~ ¹⁶⁻²⁵ are rejected under 35 U.S.C. 103(a) as being unpatentable over Coghlan et al. (WO 94/24095) in view of McChesney et al. (Transplantation, Vol. 57, no. 12, page 1717-1722) for reasons set forth in the prior office action.

Response to the Arguments

Applicant's amendments and remarks are persuasive to overcome the claim objection and claim rejection under 35 U.S.C 112. However, the arguments and remarks are not persuasive with respect to the rejection under 35 U.S.C. 103 for reasons discussed below.

1. Applicants' assertion that Weithmann reference would not render obviousness of instant claims because: a) Weithmann does not expressly disclose leflunomide as viral replication inhibitor; b) Weithmann does not teach employing A771726; and c) Weithmann does

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not provide experimental results constituting credible scientific basis for therapeutic utility in animal. The assertion is not proper. Note Weithmann teaches expressly the usefulness of leflunomide for treating viral infection disease, rendering the employment of leflunomide for treating viral infection obvious. Note the instant claims are directed to affecting a biochemical pathway with an old and well-known compound. The argument that such claims are not directed to the old and well known ultimate utility (treating viral infection) for the compounds, e.g., HWA 486, are not probative. It is well settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to *In re Swinehart*, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." Additionally, in the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates. The ultimate utility for the claimed compounds is old and well known rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103. Note, treating a disease with an agent in a host would lead the agent contacting the pathogenic cell. Weithmann is not relied on for the rejection of claim 18 (or 3), therefore argument that Weithmann does not teach A771726 for treating viral infection is not relevant to the rejection. With respect to the remarks that Weithmann lack credibility, note every U.S. Patent is presumed valid, the attack of the reference is not probative. See, MPEP 716.07.

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2. With respect of rejection over Coghlan in view of Machesney, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Specifically, Coghlan teaches the leflunomide compounds are known to be useful for treating various viral infection disease, McChesney teaches that the particular compounds herein are known to be similarly useful as those compounds disclosed by Coghlan, e.g., immunosuppressant and preventing viral infection. In fact, Coghlan discloses that the compounds are similarly useful as leflunomide. See, page 2 in Coghlan.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Examiner



Shengjun Wang

May 24, 2002

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RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200